UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,546	10/29/1999	NICHOLAS P. EVERETT	INTERLINK-3.	8843

530 7590 05/07/2003

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER
MCGARRY, SEAN

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/431,546	Applicant(s) EVERETT ET AL.	
	Examiner Sean R McGarry	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *9/30/02, 11/7/02, 2/19/03* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *14-17,25-35 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18-24 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 4 **were** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 18-24 and 36-45 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification teaches chemical synthesis of Rev4, Indolicidin, Ser-Rev4, Rev4-C-Terminal fusion, Indolicidin F, and Indolicidin F-P (amide) in Examples 1-6. The specification discloses in Example 8, the stability of Rev4 to proteases in whole cell extract. Example 9 discloses that Rev4 can "confer on Magainin 2 a stability" in whole cell extracts. Example 10 discloses that REV4 protects casein from commercial

proteases in *in vitro* assays. In example 13 Rev4-related peptides which contained amino acid extensions on either the n-terminus or C-terminus (SEQ ID NO:s 5 and 6) were shown to have protease inhibiting properties while those peptides related to indolicidin had no protective effect. The specification then teaches one in the art how to make transgenic plants that express Rev4. The specification then teaches that such (Rev4 transformants) transgenic plants have increased resistance to pathogens.

The specification does not show any conferring of resistance of a protease to any specific protein via the expression from a plant transformed with a non-native DNA expressing Rev4, indolicidin, or a functional equivalent. The specification does not show that transgenic plants comprising a transgenic Rev4 confers to a protein any resistance to a protease when the protein is applied to the plant or expressed by the plant.

The instant specification has not shown by example the protection of proteins applied to a plant or plant part by the expression of a Rev4 or indolicidin based peptide on or by the plant. Applicant appear to admit, at page 2 for example, and Mourgues et al [TIBTECH Vol. 16:203-210, 5/98] appear to assert, that the expression of exogenous protein in plant do not typically have the expected properties. Applicant has shown that proteins mixed in an in vitro environment, apparently devoid of any other plant material, were protected, but it is unclear how such an example correlates to the protection of a protein in/and or on a plant or plant part where the biological environment is very different than that where the specific examples were tested. An intact plant is most compartmentalized and the artificial conditions used in the instant examples, of course is not. An intact plant is a dynamic environment with many protein interactions, for

example, where the artificial conditions used in the instant examples is static. A plant environment contains many variable which differ from plant to plant, from plant part to plant part, from plant tissue to tissue, and from cell to cell, for example. The example provided does not account for, what concentrations would need be expressed in a plant to confer protection to a particular peptide, and how does that peptide find that specific protein desired to be protected from all those in the plant environment, for example. Will the expressed protein protect all proteins in a plant, even those that need to be degraded for plant viability?

Since the art is unpredictable, the specification does not provide adequate guidance, and the specification fails to provide examples that correlate with the routine practice of the invention in view of the teachings of the specification, and since one in the art would need to engage in undue trial and error experimentation to overcome the concerns above to practice the instant invention, the instant invention is not supported by an enabling specification.

Applicant's arguments filed 9/30/02 and 11/7/02 have been fully considered but they are not fully persuasive.

The Everett declaration filed under 37 CFR 1.132, filed on 11/7/02, has been considered and the evidence provided therein is sufficient to overcome the grounds of rejection that are drawn to the activity of indolicidin in protecting a protein from protease in an in vitro environment. The declaration does not provide evidence for a protection of protease for a protein expressed by a plant of applied to a plant by a Rev4, indolicidin or

functional equivalent expressed by a plant or plant part transform with a non-native DNA expressing a Rev4, indolicidin or functional equivalent.

Applicant has argued that the Examples in the specification are adequate to enable the use of the invention since the in vitro examples provide a correlation with the instantly claimed method. Applicant argues the production of antimicrobials and their effect in pathogens to assert evidence that the compounds in the methods claimed would function to inhibit the action of proteases outside the environment in which they are produced. It is unclear how the evidence provided correlates. The action of the compound in the methods would be required to inhibit the action of proteases on a plant surface or produced in a plant, not in the gut of a pest, for example. The environment of action in the claimed method and that of the evidence provided to not appear to be correlative environments, for example.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
May 5, 2003

SEAN McGARRY
PRIMARY EXAMINER
1635